

AMENDMENT AND RESPONSE TO OFFICE ACTION

Amendment

In the Specification

Please amend the paragraph on page 16, lines 23-31 as follows:

As used herein "milnacipran" also encompasses pharmaceutically acceptable, pharmacologically active derivatives of milnacipran including both individual enantiomers of milnacipran (dextrogyral and levogyral enantiomers) and their pharmaceutically acceptable salts, mixtures of milnacipran enantiomers and their pharmaceutically acceptable salts, and active metabolites of milnacipran and their pharmaceutically acceptable salts, unless otherwise noted.

In one embodiment, milnacipran is in the form of a therapeutically equivalent dose of para-hydroxy-milnacipran (F2782) or pharmaceutically acceptable salts thereof. It is understood that in some cases dosages of enantiomers, derivatives, and metabolites may need to be adjusted based on relative activity of the racemic mixture of milnacipran.

Please amend the paragraph on page 23, lines 13-15 as follows:

The amount of active agent released in each dose will be a therapeutically effective amount. In the case of milnacipran, the total amount in the dosage form is in the range of approximately 25 to 500 mg. In one embodiment, the composition contains 25 to 500 mg milnacipran and 100 to 600 mg of modafinil.

Please amend the paragraph on page 32, line 30 to page 33, line 7 as follows:

A kit is provided wherein the once a day pulsatile release dosage form is packaged to provide a method to conveniently begin dose titration at lower doses, for example, beginning at

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25mg, gradually increasing to 50 mg, 75 mg, 100 mg, 200 mg, 400 mg, 500 mg, over a period ranging from three days up to 16 weeks. The kit wherein the packaging material may be packaged in a box, bottle, blister package, tray, or card. The kit will include a package insert instructing the patient to take a specific dose at a specific time, for example, a first dose on day one, a second higher dose on day two, a third higher dose on day three, and so on, until a maintenance dose is reached. In one embodiment, the package insert instructs the patient to take the formulation once daily before bedtime.